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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,103	11/05/2001	A. James Mixson	5627*5	7244

7590

12/12/2005

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EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 12/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,103

Applicant(s)

MIXSON, A. JAMES

Examiner

Scott D. Priebe, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Group and/or Art Unit designation of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Primary Examiner Scott D. Priebe, Ph.D., Group Art Unit 1633.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The disclosure remains objected to because of the following informalities. The specification fails to fully comply with 37 CFR 1.821(d), with respect to the failure to identify the peptides recited at page 9, lines 2-3 (or alternatively in Fig. 17) by their assigned SEQ ID NOs, i.e. SEQ ID NOs: 3 and 5.

Appropriate correction is required.

Applicant's arguments filed 5/16/05 have been fully considered but they are not persuasive. While Applicant is correct that branched peptides are not to be listed in the Sequence Listing, the peptides identified as being choices for the R group are not branched peptides, but linear peptides. Consequently, these two peptides (SEQ ID NO: 3 and 5) do fall under the requirements of 37 CFR 1.821-1.825, and must be identified where recited by their assigned SEQ ID NO as per §1.821(d). It is suggested that the corresponding SEQ ID NO be inserted into page 9, lines 2-3 immediately following the appropriate peptide sequence.

Claim Objections

Claim 11 is objected to because of the following informalities. Claim 11 has been cancelled, and the text should not included in the complete copy of the claims, 37 CFR 1.121(c)(4)(i). Appropriate correction is required, i.e. regardless of whether any new amendments are made to the claims, Applicant is required to submit a new complete listing of the claims in which the text of cancelled claim 11 is not recited.

Claims 1, 25, and 27 are objected to because of the following informalities. Recitation of “and/or” at the end of the third to last line of part (a) of each claim should be replaced with --or-- . The two exclusion limitations are mutually exclusive, i.e. a peptide cannot consist of a random His copolymer and a block copolymer of His and a non-His positively charged amino acid. The use of “and” in this context does not make sense. Appropriate correction is required.

Claims 13-21 and 45-52 are objected to because of the following informalities. These dependent claims either do not follow the independent claim from which they depend or are separated from the dependent claim from which they depend by a dependent claim that does not also depend from that same dependent claim (see MPEP § 608.01(n)). Appropriate correction is required prior to allowance of the application. This correction may be made by examiner’s amendment. Applicant is invited to suggest a final ordering of claims to appear in a patent.

Claim Rejections - 35 USC § 112

Claims 29-35, 42, 43, and 45-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims recite the limitation that at least 27% of the amino acids in the peptide are histidine. This limitation is not clearly supported by the original specification. The situation where claim 27 was amended to recite that the linear peptide contained at least 13 amino acids was supported by the specification showing a species of at least this length, and each other possible member of the range is an integral number, i.e. the range is discontinuous. However, the range of the fraction of amino acids that are histidine is a continuous range, and reflects not only a range of mole fraction of histidine but also a range of the length of the peptide. Applicant indicates that this limitation is supported by SEQ ID NO: 7. However, SEQ ID NO: 7 is 29 amino acids long, and the mole fraction of histidine in this particular peptide would not suggest to one of skill in the art that the inventors had contemplated a genus of peptide that shared one aspect of SEQ ID NO: 7, its mole fraction of histidine, but not other aspects, e.g. its length. Furthermore, the fraction of SEQ ID NO: 7 that is histidine is not 27%, but is approximately 27.586206896551724137931034482759%. Thus, SEQ ID NO: 7 would no more suggest a genus of at least about 27% histidine than it would suggest at least about 26%, 28% or 27.5%.

In claims 29 and 42, the above limitation is combined with an additional limitation that at least about 33% of the amino acids are amino acids with a net positive charge at physiological

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pH, e.g. Arg or Lys. This limitation is not clearly supported by the original specification, nor is its combination with the 27% limitation. Applicant indicates that this limitation is supported by SEQ ID NO: 15. In fact, SEQ ID NO: 15 has 1/3 of its amino acids that are Lys, not some unspecified positively charged amino acid, and 1/3 is not 33%. As with the 27% limitation, SEQ ID NO: 15 would not suggest that the inventors had contemplated a genus of peptide wherein at least about 33% of the amino acids were positively charged, any more than it would have suggested a genus where the fraction was at least about 32%, 34% or 33.3333333333%. Furthermore, Applicant has not identified any single peptide that combines both of the recited limitations, nor has Applicant pointed to any other teaching that would have directed one of skill in the art to take one characteristic of several characteristics of two different peptides and combine them as the basis for a generic invention.

In addition, the peptides upon which Applicant relies are linear. The claims embrace not only linear peptides, but also branched peptides. There is no support in the original specification for branched peptides having these mole fractions of histidine and non-histidine positively charged amino acids. Attaching the cited peptides as side groups to a peptide backbone, e.g. oligolysine, would yield a different mole fraction of histidine or positively charged amino acid in the branched peptide than that present in the cited peptides.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application

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claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 and 12-52 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/131,909. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is substantial overlap between the subject matter instantly claimed and that claimed in the '909 application. For example, the explicitly claimed embodiments of claims 11 and 18 of the '909 application and their methods of use are embraced by many of the instant claims, including claims 1, 2, 7-9, 27-30, 35, 40-42, 45, 46, and 50-52. Although not explicitly recited in the claims of the '909 application, when these claims are read in light of the '909 application, features such as the inclusion of a transition metal, lipid or intracellular delivery component or branched transport polymers comprising the subsegments recited in instant claim 3, for example, are clearly contemplated as forming part of the broader invention claimed in the '909 application, as are the methods of making and using the compositions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. However, the '909 application has been allowed. Upon

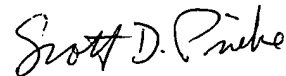
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issuance of the '909 application, the rejection will no longer be provisional. Consequently, this rejection cannot be withdrawn as per MPEP 804, section I.B., if the claims are otherwise in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Scott D. Priebe, Ph.D.
Primary Examiner
Art Unit 1633